

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant(s): Rosen et al. | |
| Application No.: 09/937,192 | Group Art Unit: 1624 |
| Filed: 9/21/2001 | Examiner: Bruck Kifle |
| Title: Methods and Compositions for Degradation and for Inhibition of HER-Family Tyrosine Kinases | Confirmation No: 6277 |
| Attorney Docket No.: MSK.P-038 | |
| Customer No.: 52334 | |

Mail Stop Patent Extension
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION TO THE DIRECTOR UNDER RULE 1.181

For Supervisory Review of the Determination of
Patent Term Extension under 35 U.S.C. 154(b) and Rule 1.701

Sir:

Applicants hereby request supervisory review of the Determination of Patent Term Extension under 35 U.S.C. 154(b) and 37 C.F.R. §1.701 indicated in the Notice of Allowance of the above-referenced application in accordance with the provisions of 37 CFR § 1.181 and 35 USC 154(b). The fee as detailed in 37 C.F.R. §1.18(e) of \$200 is included.

PRELIMINARY REMARKS:

A Notice of Allowance was mailed in this case on December 7, 2006 indicating that the patent to issue on this application is entitled to zero (0) days of patent term extension. With this paper Applicants hereby petition the Director for supervisory review of the Determination of Patent Term Extension under 35 U.S.C. 154(b) and 37 C.F.R. §1.701 and to extend the term of the patent by 1054 days, 602 days, or at the very least by 338 days.

STATEMENT OF FACTS:

The present application entered the US national stage on September 21, 2001 from a PCT application filed April 7, 2000 that claimed the benefit of a US provisional application filed on April 9, 1999. On October 10, 2003 a first Notice of Appeal was filed appealing the Examiner's indication that all claims (3, 4, 6, and 9-34) were rejected under 35 USC § 112 first and/or second paragraphs. On August 28, 2006 the BPAI rendered a decision overturning the Examiner's 112 first and second paragraph rejections. On December 7, 2006 the USPTO mailed a Notice of Allowance in this case indicating that all claims (3, 4, 6, and 9-34) were allowed and that the patent was entitled to zero (0) days of patent term extension. What follows is a summary of the relevant prosecution history of this application:

(1) 10/10/03 - Applicants filed their first Notice of Appeal appealing the Examiner's rejections of all claims (3, 4, 6, and 9-34) under 35 USC §112, first and/or second paragraphs.¹

(2) 6/25/04 - A non-final office action was mailed indicating that prosecution had been reopened and that all claims (3, 4, 6, and 9-34) were still rejected under 35 USC 112, first and/or second paragraphs.

¹ Applicants note that the USPTO lost Applicants' brief filed on December 15, 2003 in support of the present Notice of Appeal. Applicants were required to resubmit this appeal brief to the USPTO on April 23, 2004.

(3) 07/07/05 - Applicants filed their second Notice of Appeal appealing the Examiner's rejections of all claims (3, 4, 6, and 9-34) under 35 USC §112, first and/or second paragraphs.

(4) 07/11/05 - A non-final office action was mailed indicating that all claims (3, 4, 6, and 9-34) were still rejected under 35 USC 112, first and/or second paragraphs.

(5) 09/25/05 - Applicants filed their third Notice of Appeal appealing the Examiner's rejections of all claims (3, 4, 6, and 9-34) under 35 USC §112, first and/or second paragraphs.

(6) 08/28/06 - The BPAI's Decision on Appeal was mailed indicating that the Examiner's rejections of all claims (3, 4, 6, and 9-34) under 35 USC §112, first and second paragraphs **were reversed**. See the Final Decision on Appeal from the BPAI attached as Exhibit A.

(7) 12/07/06 - A Notice of Allowance was mailed indicating that all claims (3, 4, 6, and 9-34) were allowed and that Applicants were entitled to zero (0) days of patent term extension under 35 U.S.C. 154 (b).

REMARKS:

The present application was filed as a PCT on April 7, 2000. The patent term extension provisions of 35 U.S.C. 154(b) are applicable to patent applications filed on or after June 8, 1995 and prior to May 29, 2000. In particular patent term extension is available when the application is subject to Appellate review and when a decision in favor of Applicant is rendered. 35 U.S.C. 154(b)(2) reads:

(2) **EXTENSION FOR APPELLATE REVIEW.** - If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

37 C.F.R. §1.701 provides further guidance on the application of 35 U.S.C. 154(b) and the calculation of patent term extension and states:

(3) The **period of delay** under paragraph (a)(3) [35 U.S.C 154(b)(2)] of this section is the sum of the number of days, if any, in **the period beginning on the date on which an appeal to the Board of Patent Appeals and Interferences was filed** under 35 U.S.C. 134 **and ending on the date of a final decision in favor of the applicant** by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

Therefore the two questions that need to be answered by the Director are:

- (1) Was there a Final Decision in favor of Applicant by the BPAI?
- (2) What is the sum number of days of patent term extension available to Applicants?

Answer (1): YES, there was a final decision rendered by the BPAI in favor of applicants.

A final decision on Appeal was rendered by the BPAI and mailed in this case on August 28, 2006. *See* paragraph (6) of the statement of facts. *See also* attached Exhibit A. The decision indicated that the Examiner's rejections of all claims (3, 4, 6, and 9-34) under 35 USC §112, first and second paragraphs **were reversed**. The Court stated that, "[b]ecause the examiner has failed to set forth a prima facie case of upatentability under 35 U.S.C. § 112, first or second paragraph, the rejections under those sections of the statute are reversed." *Id. at* page 8.

The Board however affirmed the Examiner's provisional double patenting rejection. However, this rejection was never an issue in the present appeal and Applicants did not even argue against it. This rejection is now irrelevant as the cited application has not issued.

Answer (2): Applicants are entitled to patent term extension of 1054 days, 602 days, or at the very least 338 days.

Applicant's filed their first Notice of Appeal in this case on October 10, 2003 appealing the Examiner's determination that all claims (3, 4, 6, and 9-34) were rejected under 35 USC §112, first and/or second paragraphs. *See* paragraph (1) of the statement of facts. Despite further office actions, responses, and Notices of Appeal, Applicants failed to overcome these 112 rejections without Appellate review. The final decision rendered by the BPAI in this case **reversed** the Examiner's determination that all claims (3, 4, 6, and 9-34) were unpatentable under both 35 USC §112, first and second paragraphs. *See* paragraph (6) of the Statement of Facts.

According to the law, the number of days of patent term extension available to Applicants is the sum of the number of days, "in the period **beginning** on the date on which an appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and **ending** on the date of a final decision in favor of the applicant." *See* 37 CFR §1.701. Applicants submit that they are entitled to the number of days in this case from their first filed Notice of Appeal, appealing the Examiner's 112 first and second paragraph rejections of all claims, to the final decision by the BPAI that overturned these rejections. This translates to **1054 days** of patent term extension for the time between October 10, 2003 to August 28, 2006, inclusive.

Applicants' note, however, that during this time period the Examiner reopened prosecution of the application while maintaining the same rejections. Applicants submit that if the Director determines that Applicants are not entitled to the full amount of 1054 days of patent term extension, that it is found that they are entitled to number of days that prosecution was suspended. This translates to 602 days of patent term extension and is calculated as:

The 1st Notice of Appeal (October 10, 2003) to the mailing of the next office action (June 25, 2004). **260 Days**

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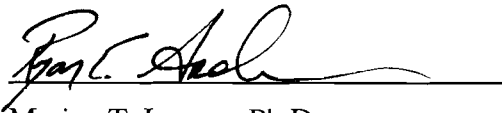
The 2nd Notice of Appeal (July 7, 2005) to the mailing of the next office action (July 11, 2005). **4 Days**

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The 3rd Notice of Appeal (September 25, 2005) to the final decision of the BPAI in favor of Applicants (August 28, 2006). **338 days.**

At the very least Applicants are entitled to **338 days** of patent term extension (i.e. the number of days from their third Notice of Appeal until the BPAI's final decision in this case). However, because the Examiner maintained his 112 first and second paragraph rejections of all claims from the filing of the first Notice of Appeal until the BPAI's final determination of this issue, Applicants submit that they are entitled to the full amount of 1054 days. In the alternative Applicants submit that they are entitled to the number of days that prosecution was suspended, which is 602 days. Such action is earnestly solicited.

Respectfully submitted,



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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

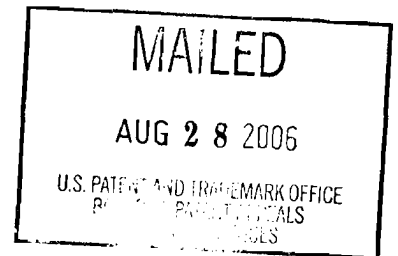
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte NEAL ROSEN, SCOTT D. KUDUK,
SAMUEL J. DANISHEFSKY, FURZHONG F. ZHENG,
LAURA SEPP-LORENZINO, and OUATEK OUERFELLI

Appeal No. 2006-1468
Application No. 09/937,192

HEARD: JULY 11, 2006



Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 4, 6 and 9-34. Claims 3, 12 and 13 are representative of the claims on appeal, and read as follows:

3. A chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.

Ex. A

12. A method for destruction of cells expressing a HER-family tyrosine kinase, comprising administering to the cells a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.
13. A method for treating cancer in a patient suffering from cancer, comprising administering to the patient a therapeutic composition comprising a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.

Claims 12-30 and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not enable the full scope of the claimed subject matter. In addition, claims 3, 4, 6 and 9-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Finally, 3, 4, 6 and 9-34 stand provisionally rejected under the judicially created doctrine of obviousness-type patenting as being unpatentable over claims 1, 2, 6, 7, 12, 13 and 15-40 of copending application 09/960,665. As appellants do not argue the merits of the provisional obviousness-type double patenting rejection, we summarily affirm that rejection. After careful review of the record and consideration of the rejections under 35 U.S.C. § 112, first and second paragraphs, we reverse.

DISCUSSION

Claims 12-30 and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph,

because the specification, while being enabling as a method of treating HER-2 expressing cancer using geldanamycin dimer linked by a 4-carbon chain at the 17-positions of each, does not reasonably provide enablement for treating any and all cancers and for destruction of other cells or treating cancers generally using “a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.”

Examiner's Answer, page 3.

“[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). “[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.” Id. at 224, 169 USPQ at 370. Here, the examiner has not provided

“acceptable evidence or reasoning which is inconsistent” with the specification, and therefore has not met the initial burden of showing nonenablement.

While the examiner engages in a Wands analysis, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) (noting that facts that should be considered in determining whether a specification is enabling include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims), the examiner's primary concern appears to be that “[t]here is no general treatment for cancer and there is no correlation between the assays relied upon by applicants and the ability to treat all cancers.” Examiner's Answer, page 4. The examiner states:

The claims are drawn to disorders that are not related and whose treatment using a single compound is unknown. Pancreatic cancer, for example, has proven extremely difficult to treat. Gastric cancer embraces several different types of cancers which includes, Adenocarcinomas (cancers started in the gland cells in the stomach lining), Squamous cells cancers are cancers in the skin-like cells that are mixed with gland cells to make the stomach lining, Lymphomas, sarcomas (cancer that begins in the muscle layer of the stomach is sarcoma) and Neuroendocrine tumours (cancers that grow in hormone producing tissues, usually in the digestive system). Treatment for each is different.

Id. at 6. The examiner, however, provides no evidence to support the above.¹

The examiner also asserts that there is no predictability because the invention is pharmaceutical in nature, and that “the amount of guidance presented in the specification as to which compounds are sufficiently active to be useful for the claimed uses is nonexistent.” Id. at 5. Again, the examiner has provided no evidence or scientific reasoning to support those assertions, and thus has not met his burden in demonstrating that the specification fails to enable the full scope of the claimed subject matter. In addition, the treatment of “any and all cancers” is not the proper standard as a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971).

Moreover, appellants have provided evidence demonstrating that a monomeric ansamycin compound, as well as other hsp90 inhibitors “are efficacious in a variety of tumor types including breast cancer, ovarian cancer, pancreatic cancer and gastric cancer . . . , other HER kinase overexpressing tumors, and tumors which do not over express HER kinase.” See Appeal Brief,

¹ The examiner does cite Sreedhar et al., Biochimica et Biophysica Acta, pp. 233-242 (2004). Appellants state in the Reply Brief that the Sreedhar reference is not of record, and we also could not find it in our review of the record. In response, the examiner merely stated that “[t]he reply brief . . . has been entered and considered.” Paper mailed February 17, 2006. Thus, we have not considered the examiner’s arguments to the extent that they rely upon the Sreedhar reference.

page 9, as well as the references cited by Appellants on that page. Again, the examiner has not brought in any evidence or provided any scientific reasoning to refute the evidence provided by appellants.

Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

Claims 3, 4, 6 and 9-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that appellant regards as the invention. See examiner's Answer, page 7.²

The examiner's first concern is that "[t]he metes and bounds of . . . 'ansamycin' are unknown." As noted by appellants, however, "[t]he term 'ansamycin antibiotic' is a recognized term of art," see Appeal Brief, page 12,³ and the examiner has provided no evidence to demonstrate that there is confusion in the art regarding that term.

The examiner's second concern is that the nature of the linker is unknown. See Examiner's Answer, page 7. As noted by appellants, see Appeal Brief, page 14, the specification at page 4 and page 6, describe the linker, and how activity varies with linker length. Thus, we find that one skilled in the art

² The examiner designates this rejection as a "New Grounds of Rejection." See Examiner's Answer, page 7. As noted by appellants, however, see Reply Brief, page 1, the rejection appeared in the non-final rejection mailed July 11, 2005.

³ See also Rinehart, "Antibiotics with Ansa Rings," Accounts of Chemical Research, Vol. 5, pp. 57-64 (1972), attached to the Appeal Brief, which discusses the then new class of ansamycin antibiotics.

would understand the metes and bonds of the term linker. See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987) (noting that claims are in compliance with 35 U.S.C. § 112, second paragraph, if “the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits.”).

The examiner’s third concern is with the term bind. According to the examiner, “[t]he term ‘bind’ in the claims is indefinite. There is no way of knowing whether a given compound would bind. Binding is a process which cannot be observed, merely inferred, which is unreliable.” Examiner’s Answer, page 8. We cannot understand the examiner’s concern in this regard, however, because “bind” is an art recognized term, and it is unclear if “bind” is unacceptable, what term would be acceptable to the examiner.

Finally, the examiner objects to the term “retain the ability to bind,” asserting that it is unclear. According to the examiner:

Does it mean that the compound is supposed to bind exactly as strongly as the monomer binds or does it mean that it simply needs to bind? Both definitions could be valid, but Appellants need to clarify whether the term “retain” means as strongly or weakly as the monomer or simply the ability with no regard as to how it accomplishes the binding.

Id.

From the examiner’s statement that “[b]oth definitions” he proposes are valid, the examiner understands what is meant by the phrase “retain the ability to bind.” The examiner’s concern thus appears to be the breadth, however, “breadth is not to be equated with indefiniteness.” In re Miller, 441 F.2d 689,

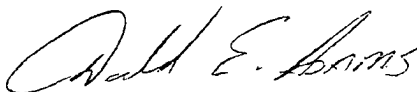
693, 169 USPQ 597, 600 (CCPA 1971); see also In re Hyatt, 708 F.2d 712, 714-15, 218 USPQ 195, 197 (Fed. Cir. 1983).

For the reasons set forth above, the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, second paragraph, is reversed.


CONCLUSION

Because the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first or second paragraph, the rejections under those sections of the statute are reversed. Because appellants do not argue the merits of the provisional obviousness-type double patenting rejection, we summarily affirm that rejection.

AFFIRMED


Donald E. Adams
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge


Lora M. Green
Administrative Patent Judge

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Appeal No. 2006-1468
Application No. 09/937,192

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Marina Larson & Associates, LLC
Re: MSK
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